

### REMARKS

Claims 1-37 were previously pending. Claims 1-23 were previously elected in response to a restriction requirement. Claims 24-37 are currently canceled and claims 38-51 are added. Reconsideration of claims 1-23 and 38-51 is requested in light of the above amendments and the following remarks.

#### **§103 Rejections**

**Claims 1-16, 19, and 21-23** stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,951,561 to Pepper et al. (“Pepper”) in view of U.S. Patent No. 6,270,499 to Leu et al. (“Leu”). Applicants respectfully traverse these rejections on the grounds that these references are defective in establishing a prima facie case of obviousness with respect to claims 1-16, 19, and 21-23.

As the PTO recognizes in MPEP § 2142:

*... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...*

It is submitted that the examiner has not factually supported a prima facie case of obviousness in the present case.

The PTO provides in MPEP §2142:

*...[T]he examiner must step backward in time and into the shoes worn by the hypothetical “person of ordinary skill in the art” when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention “as a whole” would have been obvious at that time to that person ...*

With respect to independent claim 1, Pepper and Leu simply do not teach, or even suggest, the desirability of the combination of elements recited. Independent claim 1 requires “gaining supra patella surgical access to an intramedullary canal of a proximal end of a tibia.” In this regard, the Examiner recognized that Pepper fails to disclose

“insertion of an intramedullary nail using supra patellar surgical access.” However, the Examiner fails to cite a reference teaching “gaining supra patella surgical access to an intramedullary canal of a proximal end of a tibia” as required by claim 1.

The Office Action notes:

“Leu et al. teach insertion of an intramedullary nail or fixation member in the intramedullary canal of a tibia wherein the intramedullary nail is anchored to the tibia by means of screws at non-perpendicular angles to one another and to the fixation member (Figs. 1 and 4, col. 3, lines 47-67 and col. 4, lines 1-45).

“It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the Pepper et al. method to gain supra patellar access to the intramedullary canal of a tibia for insertion of an intramedullary nail, as taught by Leu et al., for fracture fixation.”

However, the Office Action does not point to and Applicant could not find any portion of Leu et al. teaching or suggesting a surgical method of tibial fixation performed by gaining supra patellar surgical access to a tibia. In fact, as evident from the lack of illustration of a patella in the figures and the corresponding lack of description, Leu et al. fails to reference the surgical access site relative to the patella. Thus, Leu simply fails to teach or suggest “gaining supra patella surgical access to an intramedullary canal of a proximal end of a tibia” as required by claim 1. Further, Applicant has submitted herewith an excerpt from *Campbell's Operative Orthopaedics* (7<sup>th</sup> Edition) for consideration by the Examiner. In particular, Figs. 44-37 through 44-42 and the corresponding text illustrate the insertion of an intramedullary nail into the intramedullary canal of a tibia using an infra-patellar (below the knee cap) surgical access. Applicant asserts that the excerpt shows the known surgical approach and the state of the art prior to Applicant's current invention. Therefore, without some teaching or motivation to deviate from this technique, it would not have been obvious to one skilled in the art at the time of the invention to use a supra patella surgical approach to gain access to an intramedullary canal of a tibia.

Thus, for at least these reasons the Examiner has not factually supported a prima facie case of obviousness with respect to claim 1. Claims 2-16 depend from and further limit claim 1 and, therefore, Examiner has not factually supported a prima facie case of obviousness with respect to those claims for at least the same reasons.

Similarly, independent claim 19 requires “creating a supra patella surgical access site.” Thus, for at least the same reasons as stated above with respect to claim 1 the Examiner has not factually supported a prima facie case of obviousness with respect to claim 19. Claims 21-23 depend from and further limit claim 19 and, therefore, Examiner has not factually supported a prima facie case of obviousness with respect to those claims for at least the same reasons.

**Claims 17, 18, and 20** stand rejected under 35 U.S.C. §103(a) as being unpatentable over Pepper and Leu in further view of U.S. Patent No. 6,036,696 to Lambrecht et al. (“Lambrecht”) and U.S. Patent No. 6,189,788 to Sullivan (“Sullivan”). However, claims 17 and 18 depend from and further limit claim 1, and claim 20 depends from and further limits claim 19. Therefore, the Examiner has not factually supported a prima facie case of obviousness with respect to claims 17, 18, and 20 for at least the same reasons as those set forth above with respect to claims 1 and 19.

#### **New Claims 38-51**

New claims 38-51 have been added. These claims are clearly patentable over the cited references.

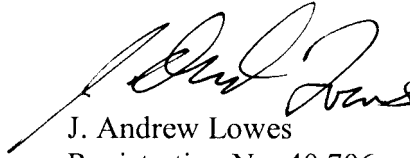
In particular, claim 38 recites in part, “creating a percutaneous incision above a patella” and “inserting the distal portion of the sheath through the incision to a position adjacent a proximal portion of a tibia.” As shown above, Pepper, Leu, Lambrecht, and Sullivan simply do not teach creating an incision above the patella, nor inserting a sheath to a position adjacent the tibia through an incision above the patella. Claims 39-44 depend from and further limit independent claim 38. Thus, for at least these reasons claims 38-44 are patentable over the cited references.

Similarly, claim 45 recites in part, “creating a suprapatellar percutaneous incision” and “inserting a sheath through the incision posterior to the patella such that a distal portion of the sheath is positioned adjacent a proximal portion of the tibia.” Again, Pepper, Leu, Lambrecht, and Sullivan do not teach such limitations. Claims 46-51 depend from and further limit independent claim 45. Thus, for at least these reasons claims 45-51 are patentable over the cited references.

### CONCLUSION

It is believed that all pending claims 1-23 and 38-51 are in condition for allowance. An early indication of allowance of all claims is hereby requested. Should the Examiner decide that an interview would expedite consideration of the claims, please contact the undersigned at the number below.

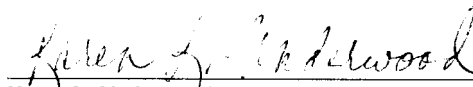
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